
EXHIBIT 9

Patent Term Extension Calculations for
Patent Term Extension of
U.S. Patent No. 5,565,467

Patent Term Extension Calculation for U.S. Patent No. 5,565,467

Patent Issue Date: 15 Oct 1996

Period of Testing Phase – IND 47,838

24 April 1995 through

20 December 2000 is:

24 Apr 95 – 23 Apr 96 =	366
24 Apr 96 – 23 Apr 97 =	365
24 Apr 97 – 23 Apr 98 =	365
24 Apr 98 – 23 Apr 99 =	365
24 Apr 99 – 24 Apr 00 =	366
24 Apr 00 – 23 May 00 =	29
24 May 00 – 23 Jun 00 =	31
24 Jun 00 – 23 Jul 00 =	30
24 Jul 00 – 23 Aug 00 =	31
24 Aug 00 – 23 Sep 00 =	31
24 Sep 00 – 23 Oct 00 =	30
24 Oct 00 – 23 Nov 00 =	31
24 Nov 00 – 20 Dec 00 =	27
	<u>2067 days</u>

Period of IND post-patent issuance

24 April 1995 through

15 October 1996 is:

24 Apr 95 – 23 Apr 96 =	365 days
24 Apr 96 – 23 May 96 =	29
24 May 96 – 23 Jun 96 =	31
24 Jun 96 – 23 Jul 96 =	30
24 Jul 96 – 23 Aug 96 =	31
24 Aug 96 – 23 Sep 96 =	31
24 Sep 96 – 15 Oct 96 =	<u>22</u>
	539 days

Applicable Period of Testing Phase

2067 days – 539 days = 1528 days

Testing Phase

IND Phase / 2 = 1528 / 2 = 764 days

Period of Approval Phase – NDA 21-319

NDA Submission Date: 21 Dec 2000

NDA Approval Date: 20 Nov 2001

Period of Approval Phase:

21 Dec 00 – 31 Dec 00 =	10
1 Jan 01 – 31 Jan 01 =	31
1 Feb 01 – 29 Feb 01 =	28
1 Mar 01 – 31 Mar 01 =	31
1 Apr 01 – 30 Apr 01 =	30
1 May 01 – 31 May 01 =	31
1 Jun 01 – 30 Jun 01 =	30
1 Jul 01 – 31 Jul 01 =	31
1 Aug 01 – 31 Aug 01 =	31
1 Sep 01 – 30 Sep 01 =	30
1 Oct 01 – 31 Oct 01 =	31
1 Nov 01 – 20 Nov 01 =	<u>20</u>
	334 days

IND phase/2 + NDA phase = 764+334 = 1098

Total Patent Term Extension: 1098 days

Expiration + 1098-Day Patent

Term Extension: 18 Oct 2016

14 Year Cap from NDA Approval Date:

NDA Approval Date + 14 yrs =

20 Nov 01 + 14 yrs = 20 Nov 2015

14 year Patent Term Cap applies.

Patent Term Extension subject to 14 Year

Cap: 769 days

Expiry with Extension: 20 Nov 2015